Anutra Medical Inc.
c/o Cameron Perkins
1000 Perimeter Pike, Suite E
Morrisville, NC 27560

Re: K143757
  Trade/Device Name: Anutra Feedback Aspiration Syringe
  Regulation Number: 21 CFR 880.5860
  Regulation Name: Piston Syringe
  Product Code: FMF
  Regulatory Class: II
  Dated: December 18, 2014
  Received: December 31, 2014

Dear Cameron Perkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
<table>
<thead>
<tr>
<th><strong>Indications for Use</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Name</strong></td>
<td>ANUTRA Feedback Aspiration Syringe</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The ANUTRA Feedback Aspiration Syringe is intended for use by healthcare professionals for general purpose fluid aspiration/injection.</td>
</tr>
<tr>
<td><strong>Type of Use</strong></td>
<td>Prescription Use (Part 21 CFR 801 Subpart D)</td>
</tr>
<tr>
<td><strong>Due Date</strong></td>
<td></td>
</tr>
<tr>
<td><strong>FOR FDA USE ONLY</strong></td>
<td></td>
</tr>
<tr>
<td>Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)</td>
<td></td>
</tr>
</tbody>
</table>

This section applies only to requirements of the Paperwork Reduction Act of 1980.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 70 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
5.0 510(k) Summary

K143757

5.1. Submitter Information

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Date Summary Prepared: December 18, 2014

5.2. Device Identification

Trade/Proprietary Name: ANUTRA Feedback Aspiration Syringe
Common Name: Control Syringe
Classification Name: Piston Syringe
21CFR 880.5860, Class II
Classification Panel: General Hospital
Product Code: FMF (Syringe, piston)
5.3. **Predicate Device**

The ANUTRA Feedback Aspiration Syringe is substantially equivalent to the following predicate device:

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>510(k)</th>
<th>Date Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Single Use, Hypodermic Syringe</td>
<td>Becton, Dickinson and Company</td>
<td>K110771</td>
<td>May 13, 2011</td>
</tr>
</tbody>
</table>

5.4. **Device Description**

The ANUTRA Feedback Aspiration Syringe is a piston syringe (control syringe) consisting of a plastic barrel which contains a printed graduated scale (5mL nominal volume) and 6% male Luer Lock connection, a plunger, and a plastic plunger rod. The internal surface of the ANUTRA Feedback Aspiration Syringe barrel is lubricated with polydimethylsiloxane (silicone). The plunger rod design contains a finger ring to allow for ease of use, and tab features with interface with the barrel to provide audible and tactile feedback to the user.

The ANUTRA Feedback Aspiration Syringe is single-use only, non-pyrogenic, and sterilized by gamma irradiation.

5.5. **Intended Use**

The ANUTRA Feedback Aspiration Syringe is intended for use by healthcare professionals for general purpose fluid aspiration/injection.

5.6. **Predicate Device Comparison – Technical Characteristics**

Equivalency of technical characteristics is demonstrated through a direct comparison of the ANUTRA Feedback Aspiration Syringe and the predicate device listed in the table below.

<table>
<thead>
<tr>
<th>Technical Characteristic</th>
<th>Subject Device: ANUTRA Feedback Aspiration Syringe</th>
<th>Predicate Device: BD Single Use, Hypodermic Syringe (K110771)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrel</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Plunger Rod</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Plunger</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Luer Configuration</td>
<td>Luer Lock</td>
<td>1mL – Luer Slip</td>
</tr>
<tr>
<td>Nominal Fluid Volume</td>
<td>5mL</td>
<td>1mL, 3mL and 5mL</td>
</tr>
<tr>
<td>Lubrication</td>
<td>Polydimethylsiloxane (silicone)</td>
<td>Unknown, device assumed to be lubricated</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Gamma irradiation</td>
<td>Ethylene oxide or gamma irradiation</td>
</tr>
</tbody>
</table>
The predicate device is a piston syringe. The ANUTRA Feedback Aspiration Syringe is a type of piston syringe (specifically, a control syringe). The intended use for the ANUTRA Feedback Aspiration Syringe is the same as its predicate device, the BD Single Use, Hypodermic Syringe (K110771).

**Barrel**
The volume of fluid contained within the both the ANUTRA Feedback Aspiration Syringe and the predicate device is indicated by graduation marks printed on the outside of the barrel. The ANUTRA Feedback Aspiration Syringe has a plastic barrel with a 5mL nominal fluid volume. A 5mL variant of the predicate device contains the same nominal volume.

**Luer Configuration**
Both the subject device and the predicate device are offered in a male Luer Lock configuration. The predicate device is also available in a Slip Luer configuration (1mL only).

**Nominal Fluid Volume**
The nominal fluid volume for both the subject device and the predicate device is 5mL. The predicate device is also available in other fluid volumes.

**Lubrication**
The internal surface of the ANUTRA Feedback Aspiration Syringe is coated with a polydimethylsiloxane (silicone). The predicate device 510(k) summary does not specify whether or not the predicate device is lubricated, however based on an inspection of the predicate device, it is believed to be lubricated.

**Plunger Rod & Plunger**
Both the subject device and the predicate device have a plastic plunger rod and a synthetic rubber plunger; the plunger is attached to the plunger rod with snap-fit retention features. The ANUTRA Feedback Aspiration Syringe plunger rod contains features which provide audible and tactile feedback when the plunger is advanced or retracted, and a finger ring for ease of use and handling the device. The predicate device has a flat push-button on the end of its plunger rod. The mechanism for delivery of fluid is the same for both the subject device and predicate devices.

**Sterilization Method**
The ANUTRA Feedback Aspiration Syringe is sterilized using gamma irradiation. The predicate device can be sterilized by either gamma irradiation or ethylene oxide.
**Materials**
The ANUTRA Feedback Aspiration Syringe is constructed of the following polymeric components:

- Barrel: Polypropylene copolymer
- Plunger Rod: Polypropylene copolymer
- Plunger: Synthetic (polyisoprene) rubber
- Lubrication: Polydimethylsiloxane (silicone)

The subject device has been tested and meets the biological requirements outlined in ISO 10993-1. A summary of these test results is provided in Section 15 – Biocompatibility.

5.7. **Predicate Device Comparison – Performance Characteristics**
The performance data supplied with this submission demonstrates that the ANUTRA Feedback Aspiration Syringe meets the specified requirements and is substantially equivalent to the predicate device.

The predicate device (BD Single Use, Hypodermic Syringe) provided an overview of testing completed in the 510(k) Summary (K110771). These tests were used to compare the subject device and the predicate device performance.

Tests Performed on Subject Device and Predicate Device (as indicated in the predicate device 510(k) Summary):
- ISO 7886-1
  - Section 6 (Limits for Acidity or Alkalinity)
  - Section 7 (Limits for Extractable Metals)
  - Annex D Liquid leakage at syringe piston under compression
  - Annex G Forces to operate the plunger

Tests Performed on Subject Device:
- ISO 7886-1
  - Section 5 (Cleanliness)
  - Section 8 (Lubricant)
  - Section 9 (Tolerance on graduated capacity)
  - Section 10 (Graduated Scale)
  - Section 11 (Barrel)
  - Section 12 (Piston/plunger assembly); Annex B
  - Section 13 (Nozzle)
  - Section 14.1 (Dead Space)
  - Section 14.2 (Freedom from air and liquid leakage past piston); Annex B and Annex D
  - Section 15 (Packaging)
  - Section 16 (Labeling)
ISO 594-2
- Section 3 (Dimensions and tolerances)
- Section 4.1 (Gauging)
- Section 5.2 (Liquid leakage from fitting assembly under pressure)
- Section 5.3 (Air leakage into fitting assembly during aspiration)
- Section 5.4 (Separation force of fitting assembly)
- Section 5.5 (Unscrewing torque of fitting assembly)
- Section 5.6 (Ease of assembly)
- Section 5.7 (Resistance to overriding)
- Section 5.8 (Stress cracking)

Sterile Barrier Packaging Testing
- ASTM F2096 – 11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

General performance
- Syringe package shall be easy to open with gloved hands
- Syringe shall be able to aspirate and deliver using one hand
- Tactile feedback
- Finger reach

Biocompatibility Testing (ISO 10993)
- Cytotoxicity by Elution Test (Cytotoxicity)
- Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
- Maximization Test for Delayed Hypersensitivity (Sensitization)
- Acute Systemic Toxicity (Systemic Toxicity (Acute))
- Evaluation of Hemocompatibility: Interaction with Blood (Hemocompatibility/Hemolysis)

5.8. Conclusion
Test results demonstrated that the ANUTRA Feedback Aspiration Syringe is as safe, as effective and performs as well as or better than the legally marketed predicate device (BD Single Use, Hypodermic Syringe).

Based on comparisons of the device’s intended use, technology and performance characteristics, the ANUTRA Feedback Aspiration Syringe is substantially equivalent to the indicated predicate device. Any differences between the ANUTRA Feedback Aspiration Syringe and the predicate device have no significant influence on safety or effectiveness.